ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 08/09/2016

ClinicalTrials.gov ID: NCT00949910

Study Identification

Unique Protocol ID:	MO18109
Brief Title:	An Expanded Access Program of Tarceva (Erlotinib) in Participants With Advanced Non-Small Cell Lung Cancer (NSCLC)
Official Title:	An Expanded Access Program of Tarceva (Erlotinib) in Patients With Advanced Stage IIIB/IV Non-Small Cell Lung Cancer
Secondary IDs:	2004-000564-28 [EudraCT Number] INC-9042 [INC Research Netherlands BV]

Study Status

Record Verification:	July 2016
Overall Status:	Completed
Study Start:	November 2004
Primary Completion:	April 2009 [Actual]
Study Completion:	April 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? No

	Delayed Posting?
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 2004-25 Board Name: Martini Hospital Ethics Committee Board Affiliation: Unknown Phone: Email: e.rusch@mzh.nl
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Netherlands: Medicines Evaluation Board

Study Description

Brief Summary:	This study will provide treatment with erlotinib to participants with advanced NSCLC who have received at least one course of standard chemotherapy or radiation therapy, or who are not medically suitable for either. Efficacy and safety will be monitored throughout the study.
Detailed Description:	

Conditions

Conditions:	Non-Small Cell Lung Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 6586 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Erlotinib Erlotinib will be given as a single agent in this expanded access program (EAP) to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Treatment will continue until unacceptable toxicity, disease progression, or withdrawal for any other reason.	Drug: Erlotinib Erlotinib will be given orally as 150 milligrams (mg) once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. Other Names: • Tarceva

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Adults greater than or equal to (≥) 18 years of age
- Histologically or cytologically documented inoperable, locally advanced, metastatic, or recurrent NSCLC
- Previous treatment with no more than 2 prior chemotherapy regimens

Exclusion Criteria:

- Previous systemic anti-cancer therapy with human epidermal growth factor receptor 1 (HER1)/epidermal growth factor receptor (EGFR) inhibitors
- Inability to take oral medication
- Any other malignancies within 5 years

Contacts/Locations

Study Officials: Clinical Trials
Study Chair

Hoffmann-La Roche

Locations: Venezuela
Caracas, Venezuela, 1060

Thailand
Bangkok, Thailand, 10700

Austria
Wien, Austria, 1090

Thailand
Bangkok, Thailand, 10330

Bangkok, Thailand, 10110

Netherlands
Amsterdam, Netherlands, 1066 CX

Switzerland
Locarno, Switzerland, 6601

Netherlands
Capelle Ad Yssel, Netherlands, 2906 ZC

Switzerland
Chur, Switzerland, 7000

Netherlands
Amsterdam, Netherlands, 1091 AC

Zwolle, Netherlands, 8011 JW

Groningen, Netherlands, 9728 NZ

Eindhoven, Netherlands, 5623 EJ

Maastricht, Netherlands, 6229 HX

Hengelo, Netherlands, 7555 DL

Colombia
Bogota, Colombia

Cali, Colombia

Austria
- Wien, Austria, 1160
- Klagenfurt, Austria, 9010
- Kufstein, Austria, 6330
- Bludesch, Austria, 6712
- Wien, Austria, 1140
- Innsbruck, Austria, 6020

Netherlands
- Boxmeer, Netherlands, 5831 HA
- Harderwijk, Netherlands, 3844 DG
- Groningen, Netherlands, 9713 GZ
- Nieuwegein, Netherlands, 3435 CM
- Amersfoort, Netherlands, 3818 ES
- Haarlem, Netherlands, 2035 RC
- Rotterdam, Netherlands, 3045 PM
- Vlissingen, Netherlands, 4382 EE
- Amsterdam, Netherlands, 1007 MB

Hungary
- Budapest, Hungary, 1529
- Nyíregyháza, Hungary, 4400
- Torokbalint, Hungary, 2045
- Budapest, Hungary, 1125

Taiwan
- Tainan, Taiwan, 704
- Tainan, Taiwan, 710

Slovenia

Ljubljana, Slovenia, 1000

Peru
Lima, Peru, 13

Lima, Peru, 11

Switzerland
Aarau, Switzerland, 5001

Serbia
Belgrade, Serbia, 11000

Novi Sad, Serbia, 21000

Belgrade, Serbia, 11000

Taiwan
Kaohsiung, Taiwan, 807

Kaohsiung, Taiwan, 813

Germany
Minden, Germany, 32429

Trier, Germany, 54290

Essen, Germany, 45122

Frankfurt, Germany, 60488

Wuerselen, Germany, 52146

Mannheim, Germany, 68167

Berlin, Germany, 13353

München, Germany, 81675

Köln, Germany, 50677

Mainz, Germany, 55101

Gauting, Germany, 82131

Freiburg, Germany, 79106

Löwenstein, Germany, 74245

Amberg, Germany, 92224

Grosshansdorf, Germany, 22927

Lübeck, Germany, 23562

Oldenburg, Germany, 26121

Lostau, Germany, 39291

Muenchen, Germany, 80336

Hamburg, Germany, 22767

Osnabrück, Germany, 49076

Aurich, Germany, 26603

Dresden, Germany, 01219

Koblenz, Germany, 56073

Leverkusen, Germany, 51375

Celle, Germany, 29221

Wuppertal, Germany, 42283

Berlin, Germany, 12203

Halle (saale), Germany, 06120

Gerlingen, Germany, 70839

Giessen, Germany, 35392

Rostock, Germany, 18055

Wangen, Germany, 88239

Kassel, Germany, 34125

Ulm, Germany, 89081

Herne, Germany, 44625

Latvia
Riga, Latvia, LV-1002

Riga, Latvia, LV 1079

Peru
Lima, Peru, 18

Finland
Haemeenlinna, Finland, 13530

Joensuu, Finland, 80210

Helsinki, Finland, 00150

Helsinki, Finland, 00290

Turku, Finland, 20520

Vaasa, Finland, 65130

Kuopio, Finland, 70211

Slovakia
Bratislava, Slovakia, 825 56

Germany
Köln, Germany, 51109

Frankfurt Am Main, Germany, 65929

Nürnberg, Germany, 90419

Berlin, Germany, 13125

Leipzig, Germany, 04207

Bonn, Germany, 53113

Hamburg, Germany, 20246

Greece
Thessaloniki, Greece, 54639

Athens, Greece, 11522

Haidari, Greece, 124.61

Heraklion, Greece, 71110

Athens, Greece, 15123

Neo Faliro, Greece, 18574

Slovakia
Nitra, Slovakia, 949 88

Kosice, Slovakia, 041 90

Australia
Melbourne, Australia, 3002

Camperdown, Australia, 2050

Kurralta Park, Australia, 5037

Adelaide, Australia, 5011

Geelong, Australia, 3220

St. Leonards, Australia, 2065

Perth, Australia, 6009

Wollongong, Australia, 2500

Germany
Bad Berka, Germany, 99437

Finland
Tampere, Finland, 33520

Greece
Athens, Greece, 13122

Australia
Waratah, Australia, 2298

Melbourne, Australia, 3084

Tugun, Australia, 4224

Slovakia
Banska Bystrica, Slovakia, 975 17

Poprad, Slovakia, 058 87

Taiwan
Taipei, Taiwan, 114

Greece
Thessaloniki, Greece, 56429

Estonia
Tallin, Estonia, 11619

Austria
Linz, Austria, 4020

Leoben, Austria, 8700

Salzburg, Austria, 5020

Grimmenstein, Austria, 2840

Hungary
Budapest, Hungary, 1122

Kecskemet, Hungary, 6000

Taiwan
Kaohsiung, Taiwan, 00833

Taoyuan, Taiwan, 333

Taipei, Taiwan, 104

Taipei, Taiwan, 106

Taichung, Taiwan, 404

Hungary
Deszk, Hungary, 6772

Pecs, Hungary, 7635

Germany
Neuruppin, Germany, 16816

Flensburg, Germany, 24939

Croatia

Zagreb, Croatia, 10000

Taiwan
Taipei, Taiwan, 112

Australia
Sydney, Australia, 2031

Poland
Warszawa, Poland, 02-781

Gdansk, Poland, 80-214

Wroclaw, Poland, 53-439

Warszawa, Poland, 01-138

Zabrze, Poland, 41-843

Lublin, Poland, 20-090

Poznan, Poland, 60-569

Portugal
São Martinho do Bispo, Portugal, 3041

Porto, Portugal, 4200-072

Lisboa, Portugal, 1600

Vila Nova de Gaia, Portugal, 4400-129

Setubal, Portugal, 2910-446

Austria
Wien, Austria, 1130

Linz, Austria, 4010

Natters, Austria, 6161

Poland
Olsztyn, Poland, 10-228

Taiwan
Taichung, Taiwan, 407

Australia
Fremantle, Australia, 6160

Germany
Dortmund, Germany, 44137

Taiwan
Changhua, Taiwan, 500

Taipei, Taiwan, 00112

Switzerland
Aarau, Switzerland, 5000

Lithuania
Kaunas, Lithuania, 50009

Vilnius, Lithuania, 08660

Sweden
Uppsala, Sweden, 75185

Falun, Sweden, 79182

Lund, Sweden, 22185

Stockholm, Sweden, 17176

Göteborg, Sweden, 41345

Linkoeping, Sweden, 58185

Romania
Cluj Napoca, Romania, 400015

Bucharest, Romania, 022328

Sibiu, Romania

Timisoara, Romania, 1900

Oradea, Romania

Australia
Sydney, Australia, 2217

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Tel Aviv, Israel, 6423906

Petach Tikva, Israel, 49100

Ramat-gan, Israel, 52621

Rehovot, Israel, 76100

Zerifin, Israel, 70300

Jerusalem, Israel, 91120

Jerusalem, Israel, 91031

Haifa, Israel, 34354

Kfar Saba, Israel, 44281

Holon, Israel, 58100

Haifa, Israel, 35152

Nahariya, Israel, 22100

Beer Sheva, Israel, 8410101

Ashkelon, Israel, 78306

Safed, Israel, 13110

Switzerland
Baden, Switzerland, 5404

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Guatemala City, Guatemala, 01015

Panama
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Buenos Aires, Argentina, 1272

Buenos Aires, Argentina, 1427

Córdoba, Argentina, 5000

Salta, Argentina, 4400

Buenos Aires, Argentina, 1437

Switzerland
Luzern, Switzerland, 6004

Peru
Callao, Peru

Austria
Oberpullendorf, Austria, 7350

Ecuador
Guayaquil, Ecuador

Quito, Ecuador, 2569

Ireland
Cork, Ireland

Dublin, Ireland, 7

Galway, Ireland

Dublin, Ireland, 8

Dublin, Ireland, 9

Australia
Chermside, Australia, 4032

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Germany
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Italy
Pavia, Italy, 27100

Parma, Italy, 43100

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Genova, Italy, 16132

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Pescara, Italy, 65124

Salerno, Italy, 80124

Mirano, Italy, 30035

Nuoro, Italy, 081100

San Giovanni Rotondo, Italy, 71013

Bari, Italy, 70124

Catanzaro, Italy, 88100

Roma, Italy, 00186

Sondrio, Italy, 23100

Bollate, Italy, 20021

Lido di Camaiore, Italy, 55043

Netherlands
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Italy

- Aviano, Italy, 33081
- Modena, Italy, 41100
- Cosenza, Italy, 87100
- Pisa, Italy, 56100
- Siena, Italy, 53100
- Bologna, Italy, 40139
- Livorno, Italy, 57100
- Roma, Italy, 00168
- Roma, Italy, 00144
- Orbassano, Italy, 10043
- Candiolo, Italy, 10060
- Ancona, Italy, 60121
- Milano, Italy, 20162
- Benevento, Italy, 82100
- Taormina, Italy, 98030
- Brescia, Italy, 25123
- Roma, Italy, 00157
- Fabriano, Italy, 60044
- Napoli, Italy, 80131
- Napoli, Italy
- Torino, Italy, 10126
- Milano, Italy, 20157
- Bergamo, Italy, 24128

Trento, Italy, 38100

Perugia, Italy, 06122

Rionero in Vulture, Italy, 85028

Albania
Tirana, Albania, 1000

Germany
München, Germany, 81737

Bulgaria
Sofia, Bulgaria, 1527

Sofia, Bulgaria, 1784

Plovdiv, Bulgaria, 4004

Varna, Bulgaria, 9010

Sofia, Bulgaria, 1756

Bosnia and Herzegovina
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Banja Luka, Bosnia and Herzegovina, 78000

Austria
Wels, Austria, 4600

Netherlands
Den Haag, Netherlands, 2504 LN

Breda, Netherlands, 4819 EV

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Praha, Czech Republic, 180 00

Plzen, Czech Republic, 305 99

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Amsterdam, Netherlands, 1061 AE

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Zaandam, Netherlands, 1502 DV

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Santiago, Chile

Italy
Udine, Italy, 33100

Peru
Lima, Peru, 18

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Seoul, Korea, Republic of, 133-792

Seoul, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 135-720

Suwon, Korea, Republic of, 442-721

Pusan, Korea, Republic of, 614-735

Daegu, Korea, Republic of, 700-712

Seoul, Korea, Republic of, 135-170

Seoul, Korea, Republic of, 136-705

Seoul, Korea, Republic of, 137-040

Kyunggi-do, Korea, Republic of, 411-769

Seoul, Korea, Republic of, 138-736

Bundang City, Korea, Republic of, 463-802

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Estonia
Tartu, Estonia, 50406

Uruguay
Montevideo, Uruguay, 11600

Netherlands
Alkmaar, Netherlands, 1815 JD

Finland
Oulu, Finland, 90029

Pori, Finland, 28500

Netherlands
's Hertogenbosch, Netherlands, 5211 RW

Beverwijk, Netherlands, 1942 LE

Leiden, Netherlands, 2333 ZA

Heerlen, Netherlands, 6419 PC

Nijmegen, Netherlands, 6532 SZ

Enschede, Netherlands, 7513 ER

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Sorocaba, Brazil, 18035-300

Rio de Janeiro, Brazil, 22260-020

Salvador, Brazil, 40170-110

Fortaleza, Brazil, 60741-420

Ijui, Brazil, 98700-000

Caxias do Sul, Brazil, 95020-450

Fortaleza, Brazil, 60125-151

Fortaleza, Brazil, 60336-550

Recife, Brazil, 52012-220

Salvador, Brazil, 41810-012

Porto Alegre, Brazil, 90480-003

Porto Alegre, Brazil, 90035-001

Porto Alegre, Brazil, 90110-270

Porto Alegre, Brazil, 90610-000

Curitiba, Brazil, 80730-180

Curitiba, Brazil, 80440-080

Sao Paulo, Brazil, 01308-000

Sao Paulo, Brazil, 04122-000

Sao Paulo, Brazil, 01509-010

Sao Paulo, Brazil, 04002-030

Sao Paulo, Brazil, 01232-010

Sao Paulo, Brazil, 01406100

Sao Paulo, Brazil, 01332-000

Sao Paulo, Brazil, 05401-400

Sao Paulo, Brazil, 04521-022

Sao Paulo, Brazil, 01308-050

Santos, Brazil, 11075-350

Campinas, Brazil, 13084-759

Jaú, Brazil, 17210-080

Ribeirao Preto, Brazil, 14025-430

Rio de Janeiro, Brazil, 22031072

Rio de Janeiro, Brazil, 22359-900

Joao Pessoa, Brazil, 58040280

Rio de Janeiro, Brazil, 22410-003

Belo Horizonte, Brazil, 30150-221

Belo Horizonte, Brazil, 30180-061

Belo Horizonte, Brazil, 30150-320

Brasilia, Brazil, 70710-904

Salvador, Brazil, 41950-610

Brasilia, Brazil, 70390-150

Austria

Zams, Austria, 6511

Wien, Austria, 1145

Brazil

Belo Horizonte, Brazil, 30140-083

Sao Paulo, Brazil, 01509-900

Campinas, Brazil, 13073-400

Russian Federation

Moscow, Russian Federation, 115478

Moscow, Russian Federation, 115478

Kazan, Russian Federation, 420111

Smolensk, Russian Federation, 214000

Stavropol, Russian Federation, 355047

Moscow, Russian Federation, 107005

St Petersburg, Russian Federation, 197758

St Petersburg, Russian Federation, 197022

Kazan, Russian Federation, 420029

Krasnodar, Russian Federation, 350040

Barnaul, Russian Federation, 656049

Samara, Russian Federation, 443031

Obninsk, Russian Federation, 249036

Netherlands

Vlaardingen, Netherlands, 3136 LA

Germany

Saarbruecken, Germany, 66113

Wiesbaden, Germany, 65199

Mönchengladbach, Germany, 41063

Augsburg, Germany, 86150

Brazil

Curitiba, Brazil, 80530-010

Hong Kong

Hong Kong, Hong Kong

Hong Kong, Hong Kong

Hong Kong, Hong Kong, 852

Hong Kong, Hong Kong

Hong Kong, Hong Kong

Ireland

Dublin, Ireland

New Zealand
Hamilton, New Zealand, 3240

Romania
Bucharest, Romania, 010816

Bucharest, Romania

Suceava, Romania

Baia Mare, Romania

Hong Kong
Hong Kong, Hong Kong

Netherlands
Amstelveen, Netherlands, 1186 AH

Leiderdorp, Netherlands, 2353 GA

Veldhoven, Netherlands, 5504 DB

Drachten, Netherlands, 9202 NN

Venlo, Netherlands, 5912 BL

Russian Federation
Ufa, Russian Federation, 450054

Krasnodar, Russian Federation

Volgograd, Russian Federation, 400138

Italy
Meldola, Italy, 47014

Romania
Alba Iulia, Romania, 510073

Indonesia
Jakarta, Indonesia, 12940

Egypt
Giza, Egypt, 12568

Giza, Egypt

Cairo, Egypt, 11796

Belgium

Gent, Belgium, 9000

Boussu, Belgium, 7360

Roeselare, Belgium, 8800

Liege, Belgium, 4000

Bruxelles, Belgium, 1070

Charleroi, Belgium, 6000

Bruxelles, Belgium, 1090

Ottignies, Belgium, 1340

Gilly, Belgium, 6060

Bruxelles, Belgium, 1200

Kortrijk, Belgium, 8500

Sint-niklaas, Belgium, 9100

Oostende, Belgium, 8400

Wilrijk, Belgium, 2610

Godinne, Belgium, 5530

Haine-saint-paul, Belgium, 7100

Libramont, Belgium, 6800

Antwerpen, Belgium, 2020

Edegem, Belgium, 2650

Namur, Belgium, 5000

Blankenberge, Belgium, 8370

Genk, Belgium, 3600

Mons, Belgium, 7000

Charleroi, Belgium, 6000

Hasselt, Belgium, 3500

Hasselt, Belgium, 3500

Bruxelles, Belgium, 1000

Arlon, Belgium, 6700

Baudour, Belgium, 7331

Antwerpen, Belgium, 2018

Tielt, Belgium, 8700

Oostende, Belgium, 8400

Gosselies, Belgium, 6041

Bruxelles, Belgium, 1020

Turnhout, Belgium, 2300

Aalst, Belgium, 9300

Brasschaat, Belgium, 2930

Korea, Republic of

Seoul, Korea, Republic of, 158-710

Pusan, Korea, Republic of, 602-702

Iksan, Korea, Republic of, 570-711

Daejeon, Korea, Republic of, 301-721

Gwangju, Korea, Republic of, 501-757

Cheonan, Korea, Republic of, 330-715

Daegu, Korea, Republic of, 705-717

Seoul, Korea, Republic of, 139-706

Pusan, Korea, Republic of, 602-739

Daegu, Korea, Republic of, 700-721

Incheon, Korea, Republic of, 400-711

Busan, Korea, Republic of, 602-715

China
Shanghai, China, 200433

Australia
Malvern, Australia, 3144

Frankston, Australia, 3199

Wodonga, Australia, 3690

China
Guangzhou, China, 510080

Guangzhou, China, 510060

Malaysia
Kuala Lumpur, Malaysia, 59100

China
Beijing, China, 100730

Beijing, China, 100021

Hangzhou, China, 310022

Shanghai, China, 200030

Beijing, China, 101149

Greece
Athens, Greece, 15123

Thessaloniki, Greece, 57001

Netherlands
Arnhem, Netherlands, 6815 AD

Assen, Netherlands, 9401 RK

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Belgium
Borgerhout, Belgium, 2140

Oudenaarde, Belgium, 9700

Tournai, Belgium, 7500

Germany
Homburg/Saar, Germany, 66424

Netherlands
Sliedrecht, Netherlands, 3361 XV

Russian Federation
Tumen, Russian Federation, 625047

Netherlands
Roermond, Netherlands, 6043 CV

Belgium
Antwerpen, Belgium, 2060

Turkey
Izmir, Turkey, 35340

Istanbul, Turkey, 34300

Izmir, Turkey, 35100

Ankara, Turkey, 06590

Ankara, Turkey, 06100

Shhiye, Ankara, Turkey, 06100

Istanbul, Turkey, 34890

Ankara, Turkey, 06500

Ankara, Turkey, 06500

India
New Delhi, India, 110085

Vellore, India, 632 004

Pune, India, 411 001

Bangalore, India, 560 076

Italy
Milano, Italy, 20133

Roma, Italy, 00152

Bologna, Italy, 40138

Firenze, Italy, 50139

Messina, Italy, 98123

Feltre - Bl, Italy, 32032

Roma, Italy, 00189

Palermo, Italy, 90123

Cuneo, Italy, 12100

Salerno, Italy, 84131

India
New Delhi, India, 201 301

Hungary
Mátraháza, Hungary, 3233

Italy
Catania, Italy, 95100

Belgium
Liege, Belgium, 4000

Saudi Arabia
Riyadh, Saudi Arabia, 11426

China
Shanghai, China, 200032

Shanghai, China, 200032

Nanjing, China, 210002

Harbin, China, 150040

Beijing, China, 100053

Tianjin, China, 300060

Chengdu, China, 610041

Wuhan, China, 430030

Turkey
Ankara, Turkey, 06100

Ankara, Turkey, 06018

Russian Federation
Moscow, Russian Federation, 143423

Turkey
Istanbul, Turkey

Mexico
Acapulco, Mexico, 39850

Chihuahua, Mexico, 31238

Chihuahua, Mexico, 31000

Guadalajara, Mexico, 44340

Guadalajara, Mexico, 44220

Juarez, Mexico, 32310

Leon, Mexico, 37000

Leon, Mexico, 37160

Matamoros, Mexico, 87300

Merida, Mexico, 97150

Merida, Mexico, 97070

Mexicali, Mexico, 21100

Mexico City, Mexico, 03100

Mexico City, Mexico, 06720

Mexico City, Mexico, 14050

Mexico City, Mexico, 07360

Mexico City, Mexico, 14080

Mexico City, Mexico, 01120

Mexico City, Mexico, 01120

Mexico City, Mexico, 01120

Mexico City, Mexico, 11850

Mexico City, Mexico, 72530

Mexico City, Mexico, 89400

Mexico City, Mexico, 06700

Mexico City, Mexico, 14080

Monterrey, Mexico, 64020

Monterrey, Mexico, 64060

Monterrey, Mexico, 64380

Monterrey, Mexico, 64320

Monterrey, Mexico, 64060

Obregon, Mexico, 85100

Obregon, Mexico, 85000

Puebla, Mexico, 72530

San Luis Potosi, Mexico, 78230

Tampico, Mexico, 89120

Tijuana, Mexico, 22320

Toluca, Mexico, 52140

Torreon, Mexico, 27200

Zapopan, Mexico, 44349

Austria
Wels, Austria, 4600

Germany
Dortmund, Germany, 44137

Homburg/Saar, Germany, 66424

Italy
Bari, Italy, 70124

Firenze, Italy, 50139

Roma, Italy, 00144

Taiwan
Taoyuan, Taiwan, 333

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this expanded access program (EAP) to participants with inoperable, locally advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC). Participants were treated with 150 milligrams (mg) oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Overall Study

	Erlotinib
Started	6586
Completed	10
Not Completed	6576
Progressive Disease	3750
Symptomatic Deterioration	1088
Lost to Follow-up	100
Study Drug-Related Adverse Event	315
Participant Refusal	390
Death Due to Malignant Disease	456
Death Due to Progression/Deterioration	4
Death Due to Adverse Event	115
Death Due to Toxicity	3
Death from Unknown Cause	5
Unspecified Progression/Deterioration	13
Switched to Compassionate/Other Use	174
Switched to Commercial Treatment	4
Violation of Eligibility	23

	Erlotinib
Logistical Reasons	13
Non-Compliance	10
Prolonged Dosing Interruption	4
Adverse Event	83
Serious Adverse Event	6
Physician/Participant Decision	7
Unknown	4
No Data	9

Baseline Characteristics

Analysis Population Description

Intent-to-Treat (ITT)/Safety Population: All participants who received at least one dose of erlotinib.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Baseline Measures

	Erlotinib
Number of Participants	6586
Age, Continuous [units: years] Mean (Standard Deviation)	62.4 (11.24)
Gender, Male/Female [units: participants]	
Female	2608
Male	3978

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Objective Response According to Response Evaluation Criteria in Solid Tumors (RECIST)
Measure Description	Objective response was defined as a best overall response of either complete response (CR) or partial response (PR) as assessed by RECIST during the study. CR was defined as disappearance of all clinical and radiographic evidence of target and non-target lesions, normal tumor markers, and absence of tumor-related symptoms. PR was defined as greater than or equal to (≥) 30 percent (%) decrease in sum of longest diameter (LD) of target lesions in reference to Baseline sum LD. Response was to be confirmed ≥28 days after the initial assessment of CR or PR. The percentage of participants (in nearest integer) with objective response was reported.
Time Frame	Up to approximately 4.5 years; assessed at Baseline, according to institutional standards during treatment (up to 3.5 years), and every 6 months thereafter
Safety Issue?	No

Analysis Population Description

ITT/Safety Population.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6586
Percentage of Participants With Objective Response According to Response Evaluation Criteria in Solid Tumors (RECIST) [units: percentage of participants]	11

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Disease Control According to RECIST

Measure Description	Disease control was defined as a best overall response of either CR, PR, or stable disease (SD) as assessed by RECIST during the study. CR was defined as disappearance of all clinical and radiographic evidence of target and non-target lesions, normal tumor markers, and absence of tumor-related symptoms. PR was defined as ≥30% decrease in sum LD of target lesions in reference to Baseline sum LD. Response was to be confirmed ≥28 days after the initial assessment of CR or PR. SD was defined as neither sufficient shrinkage to qualify for PR but less than (<) 20% increase in sum LD. The percentage of participants (in nearest integer) with disease control was reported.
Time Frame	Up to approximately 4.5 years; assessed at Baseline, according to institutional standards during treatment (up to 3.5 years), and every 6 months thereafter
Safety Issue?	No

Analysis Population Description
ITT/Safety Population.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6586
Percentage of Participants With Disease Control According to RECIST [units: percentage of participants]	56

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants by Best Overall Response According to RECIST

Measure Description	Tumor response was assessed by RECIST during the study. CR was defined as disappearance of all clinical and radiographic evidence of target and non-target lesions, normal tumor markers, and absence of tumor-related symptoms. PR was defined as ≥30% decrease in sum LD of target lesions in reference to Baseline sum LD. Response was to be confirmed ≥28 days after the initial assessment of CR or PR. SD was defined as neither sufficient shrinkage to qualify for PR but <20% increase in sum LD. Disease progression or progressive disease (PD) was defined as ≥20% increase in sum LD in reference to the smallest on-treatment sum LD, or the appearance of new lesions. The percentage of participants (in nearest integer unless the percentage is <1) with each type of best overall response was reported.
Time Frame	Up to approximately 4.5 years; assessed at Baseline, according to institutional standards during treatment (up to 3.5 years), and every 6 months thereafter
Safety Issue?	No

Analysis Population Description

ITT/Safety Population.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6586
Percentage of Participants by Best Overall Response According to RECIST [units: percentage of participants]	
Complete Response (CR)	0.7
Partial Response (PR)	10
Stable Disease (SD)	45
Progressive Disease (PD)	23
Not Evaluable	3
Not Done	18
Not Known	0.0

	Erlotinib
No Data	0.3

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Death or Disease Progression According to RECIST
Measure Description	Tumor response was assessed by RECIST during the study. Disease progression or PD was defined as ≥20% increase in sum LD in reference to the smallest on-treatment sum LD, or the appearance of new lesions. The percentage of participants (in nearest integer) who died or experienced PD was reported.
Time Frame	Up to approximately 4.5 years; assessed at Baseline, according to institutional standards during treatment (up to 3.5 years), and every 6 months thereafter
Safety Issue?	No

Analysis Population Description

ITT/Safety Population; only participants with available data were included.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6580
Percentage of Participants With Death or Disease Progression According to RECIST [units: percentage of participants]	93

5. Secondary Outcome Measure:

Measure Title	Progression-Free Survival (PFS) According to RECIST

Measure Description	Tumor response was assessed by RECIST during the study. Disease progression or PD was defined as ≥20% increase in sum LD in reference to the smallest on-treatment sum LD, or the appearance of new lesions. PFS was defined as the time from start of treatment to the first event of death or PD. The median duration of PFS and corresponding 95% confidence interval (CI) were estimated by Kaplan-Meier analysis and expressed in months.
Time Frame	Up to approximately 4.5 years; assessed at Baseline, according to institutional standards during treatment (up to 3.5 years), and every 6 months thereafter
Safety Issue?	No

Analysis Population Description

ITT/Safety Population; only participants with available data were included.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6580
Progression-Free Survival (PFS) According to RECIST [units: months] Median (95% Confidence Interval)	3.3 (3.1 to 3.4)

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Died
Measure Description	The percentage of participants (in nearest integer) who died from any cause was reported.
Time Frame	Up to approximately 4.5 years; assessed continuously during treatment (up to 3.5 years) and every 6 months thereafter
Safety Issue?	No

Analysis Population Description

ITT/Safety Population.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6586
Percentage of Participants Who Died [units: percentage of participants]	81

7. Secondary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	OS was defined as the time from start of treatment to date of death for any reason. The median duration of OS and corresponding 95% CI were estimated by Kaplan-Meier analysis and expressed in months.
Time Frame	Up to approximately 4.5 years; assessed continuously during treatment (up to 3.5 years) and every 6 months thereafter
Safety Issue?	No

Analysis Population Description

ITT/Safety Population.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Measured Values

	Erlotinib
Number of Participants Analyzed	6586

	Erlotinib
Overall Survival (OS) [units: months] Median (95% Confidence Interval)	7.9 (7.6 to 8.3)

Reported Adverse Events

Time Frame	Up to approximately 4.5 years; assessed continuously during treatment (up to 3.5 years) and every 6 months thereafter
Additional Description	ITT/Safety Population. As planned only unexpected erlotinib-related adverse events (AEs) and erlotinib-related rash were to be reported, with the exception of serious adverse events (SAEs) and AEs leading to premature withdrawal which were collected regardless of causality.

Reporting Groups

	Description
Erlotinib	Erlotinib was given as a single agent in this EAP to participants with inoperable, locally advanced, recurrent, or metastatic NSCLC. Participants were treated with 150 mg oral erlotinib once daily until unacceptable toxicity, disease progression, or withdrawal for any other reason. The dose could be reduced in the event of toxicity, and some participants therefore received 50 or 100 mg once daily. The study completed after every participant had either died or been followed for 6 months after stopping erlotinib.

Serious Adverse Events

	Erlotinib
	Affected/At Risk (%)
Total	2983/6586 (45.29%)
Blood and lymphatic system disorders	
Anaemia [A] *	43/6586 (0.65%)
Anaemia folate deficiency [A] *	1/6586 (0.02%)
Anaemia of malignant disease [A] *	2/6586 (0.03%)
Disseminated intravascular coagulation [A] *	2/6586 (0.03%)
Febrile neutropenia [A] *	2/6586 (0.03%)

	Erlotinib
	Affected/At Risk (%)
Leukocytosis [A] *	1/6586 (0.02%)
Neutropenia [A] *	1/6586 (0.02%)
Normochromic normocytic anaemia [A] *	1/6586 (0.02%)
Pancytopenia [A] *	2/6586 (0.03%)
Thrombocytopenia [A] *	2/6586 (0.03%)
Cardiac disorders	
Acute myocardial infarction [A] *	12/6586 (0.18%)
Angina pectoris [A] *	3/6586 (0.05%)
Arrhythmia [A] *	4/6586 (0.06%)
Atrial fibrillation [A] *	7/6586 (0.11%)
Atrial flutter [A] *	2/6586 (0.03%)
Atrioventricular block [A] *	1/6586 (0.02%)
Cardiac arrest [A] *	13/6586 (0.2%)
Cardiac disorder [A] *	1/6586 (0.02%)
Cardiac failure [A] *	12/6586 (0.18%)
Cardiac failure acute [A] *	2/6586 (0.03%)
Cardiac failure congestive [A] *	3/6586 (0.05%)
Cardiac tamponade [A] *	2/6586 (0.03%)
Cardio-respiratory arrest [A] *	9/6586 (0.14%)
Cardio-respiratory distress [A] *	1/6586 (0.02%)
Cardiogenic shock [A] *	1/6586 (0.02%)
Cardiopulmonary failure [A] *	14/6586 (0.21%)

	Erlotinib
	Affected/At Risk (%)
Cor pulmonale [A] *	1/6586 (0.02%)
Coronary artery disease [A] *	3/6586 (0.05%)
Hypertensive heart disease [A] *	1/6586 (0.02%)
Left ventricular failure [A] *	1/6586 (0.02%)
Myocardial infarction [A] *	18/6586 (0.27%)
Myocardial ischaemia [A] *	2/6586 (0.03%)
Pericardial effusion [A] *	20/6586 (0.3%)
Pericarditis [A] *	2/6586 (0.03%)
Sinus bradycardia [A] *	2/6586 (0.03%)
Supraventricular tachycardia [A] *	2/6586 (0.03%)
Tachyarrhythmia [A] *	5/6586 (0.08%)
Tachycardia [A] *	3/6586 (0.05%)
Ventricular arrhythmia [A] *	1/6586 (0.02%)
Ventricular fibrillation [A] *	1/6586 (0.02%)
Ear and labyrinth disorders	
Vertigo [A] *	5/6586 (0.08%)
Eye disorders	
Conjunctivitis [A] *	2/6586 (0.03%)
Diplopia [A] *	2/6586 (0.03%)
Iridocele [A] *	1/6586 (0.02%)
Retinal detachment [A] *	1/6586 (0.02%)
Visual disturbance [A] *	2/6586 (0.03%)

	Erlotinib
	Affected/At Risk (%)
Gastrointestinal disorders	
Abdominal distension [A] *	4/6586 (0.06%)
Abdominal pain [A] *	32/6586 (0.49%)
Abdominal pain lower [A] *	1/6586 (0.02%)
Abdominal pain upper [A] *	6/6586 (0.09%)
Acute abdomen [A] *	3/6586 (0.05%)
Appendicitis perforated [A] *	1/6586 (0.02%)
Ascites [A] *	6/6586 (0.09%)
Colitis [A] *	2/6586 (0.03%)
Constipation [A] *	12/6586 (0.18%)
Diarrhoea [A] *	83/6586 (1.26%)
Diverticular perforation [A] *	2/6586 (0.03%)
Duodenal ulcer [A] *	1/6586 (0.02%)
Duodenal ulcer haemorrhage [A] *	1/6586 (0.02%)
Dysphagia [A] *	21/6586 (0.32%)
Enteritis [A] *	1/6586 (0.02%)
Gastric disorder [A] *	1/6586 (0.02%)
Gastric haemorrhage [A] *	2/6586 (0.03%)
Gastric perforation [A] *	3/6586 (0.05%)
Gastric ulcer [A] *	3/6586 (0.05%)
Gastric ulcer haemorrhage [A] *	3/6586 (0.05%)
Gastritis [A] *	3/6586 (0.05%)

	Erlotinib
	Affected/At Risk (%)
Gastritis erosive [A] *	2/6586 (0.03%)
Gastrointestinal disorder [A] *	6/6586 (0.09%)
Gastrointestinal haemorrhage [A] *	19/6586 (0.29%)
Gastrointestinal obstruction [A] *	1/6586 (0.02%)
Gastrointestinal perforation [A] *	1/6586 (0.02%)
Gastrointestinal ulcer perforation [A] *	1/6586 (0.02%)
Haematemesis [A] *	6/6586 (0.09%)
Haematochezia [A] *	1/6586 (0.02%)
Haemorrhoids [A] *	1/6586 (0.02%)
Ileus [A] *	8/6586 (0.12%)
Inguinal hernia [A] *	3/6586 (0.05%)
Inguinal hernia, obstructive [A] *	1/6586 (0.02%)
Intestinal obstruction [A] *	5/6586 (0.08%)
Intestinal perforation [A] *	2/6586 (0.03%)
Jejunal perforation [A] *	1/6586 (0.02%)
Large intestine perforation [A] *	1/6586 (0.02%)
Mallory-Weiss syndrome [A] *	1/6586 (0.02%)
Mechanical ileus [A] *	1/6586 (0.02%)
Melaena [A] *	6/6586 (0.09%)
Nausea [A] *	35/6586 (0.53%)
Necrotising oesophagitis [A] *	1/6586 (0.02%)
Oesophageal haemorrhage [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Oesophageal spasm [A] *	1/6586 (0.02%)
Oesophageal stenosis [A] *	2/6586 (0.03%)
Oesophageal varices haemorrhage [A] *	1/6586 (0.02%)
Oesophagitis [A] *	1/6586 (0.02%)
Pancreatitis [A] *	3/6586 (0.05%)
Pancreatitis acute [A] *	1/6586 (0.02%)
Peptic ulcer [A] *	1/6586 (0.02%)
Peritonitis [A] *	3/6586 (0.05%)
Rectal haemorrhage [A] *	3/6586 (0.05%)
Rectal polyp [A] *	1/6586 (0.02%)
Reflux oesophagitis [A] *	2/6586 (0.03%)
Small intestinal obstruction [A] *	4/6586 (0.06%)
Stomatitis [A] *	5/6586 (0.08%)
Subileus [A] *	3/6586 (0.05%)
Upper gastrointestinal haemorrhage [A] *	4/6586 (0.06%)
Vomiting [A] *	45/6586 (0.68%)
General disorders	
Asthenia [A] *	18/6586 (0.27%)
Catheter related complication [A] *	2/6586 (0.03%)
Chest discomfort [A] *	1/6586 (0.02%)
Chest pain [A] *	51/6586 (0.77%)
Condition aggravated [A] *	2/6586 (0.03%)

	Erlotinib
	Affected/At Risk (%)
Death [A] *	14/6586 (0.21%)
Disease progression [A] *	292/6586 (4.43%)
Drug withdrawal syndrome [A] *	1/6586 (0.02%)
Euthanasia [A] *	2/6586 (0.03%)
Fatigue [A] *	16/6586 (0.24%)
Gait disturbance [A] *	3/6586 (0.05%)
General physical health deterioration [A] *	195/6586 (2.96%)
Hyperpyrexia [A] *	1/6586 (0.02%)
Ill-defined disorder [A] *	14/6586 (0.21%)
Local swelling [A] *	1/6586 (0.02%)
Malaise [A] *	7/6586 (0.11%)
Mucosal inflammation [A] *	3/6586 (0.05%)
Multi-organ failure [A] *	3/6586 (0.05%)
Oedema [A] *	4/6586 (0.06%)
Oedema peripheral [A] *	5/6586 (0.08%)
Pain [A] *	33/6586 (0.5%)
Performance status decreased [A] *	8/6586 (0.12%)
Pyrexia [A] *	52/6586 (0.79%)
Sudden cardiac death [A] *	1/6586 (0.02%)
Sudden death [A] *	2/6586 (0.03%)
Ulcer [A] *	1/6586 (0.02%)
Hepatobiliary disorders	

	Erlotinib
	Affected/At Risk (%)
Bile duct obstruction [A] *	1/6586 (0.02%)
Bile duct stone [A] *	2/6586 (0.03%)
Cholecystitis [A] *	4/6586 (0.06%)
Gallbladder obstruction [A] *	1/6586 (0.02%)
Hepatic failure [A] *	2/6586 (0.03%)
Hepatic function abnormal [A] *	4/6586 (0.06%)
Hepatic pain [A] *	1/6586 (0.02%)
Hepatitis cholestatic [A] *	1/6586 (0.02%)
Hepatomegaly [A] *	1/6586 (0.02%)
Hyperbilirubinaemia [A] *	2/6586 (0.03%)
Jaundice [A] *	5/6586 (0.08%)
Liver disorder [A] *	1/6586 (0.02%)
Immune system disorders	
Anaphylactic reaction [A] *	1/6586 (0.02%)
Contrast media allergy [A] *	1/6586 (0.02%)
Infections and infestations	
Abscess [A] *	1/6586 (0.02%)
Acute tonsillitis [A] *	1/6586 (0.02%)
Anal abscess [A] *	1/6586 (0.02%)
Appendicitis [A] *	2/6586 (0.03%)
Bacterial sepsis [A] *	1/6586 (0.02%)
Biliary sepsis [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Bronchitis [A] *	14/6586 (0.21%)
Bronchitis bacterial [A] *	2/6586 (0.03%)
Bronchopneumonia [A] *	12/6586 (0.18%)
Bursitis infective [A] *	1/6586 (0.02%)
Catheter related infection [A] *	1/6586 (0.02%)
Catheter sepsis [A] *	1/6586 (0.02%)
Catheter site infection [A] *	1/6586 (0.02%)
Cellulitis [A] *	6/6586 (0.09%)
Central line infection [A] *	6/6586 (0.09%)
Cystitis [A] *	1/6586 (0.02%)
Device related infection [A] *	2/6586 (0.03%)
Diabetic gangrene [A] *	1/6586 (0.02%)
Diarrhoea infectious [A] *	1/6586 (0.02%)
Empyema [A] *	4/6586 (0.06%)
Enterocolitis infectious [A] *	2/6586 (0.03%)
Erysipelas [A] *	3/6586 (0.05%)
Extradural abscess [A] *	1/6586 (0.02%)
Febrile infection [A] *	2/6586 (0.03%)
Folliculitis [A] *	1/6586 (0.02%)
Gastroenteritis [A] *	15/6586 (0.23%)
Gastrointestinal infection [A] *	2/6586 (0.03%)
Groin abscess [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Herpangina [A] *	1/6586 (0.02%)
Herpes simplex [A] *	1/6586 (0.02%)
Herpes virus infection [A] *	1/6586 (0.02%)
Herpes zoster [A] *	3/6586 (0.05%)
Infected epidermal cyst [A] *	1/6586 (0.02%)
Infection [A] *	23/6586 (0.35%)
Infective exacerbation of chronic obstructive airways disease [A] *	1/6586 (0.02%)
Lower respiratory tract infection [A] *	20/6586 (0.3%)
Lung abscess [A] *	2/6586 (0.03%)
Lung infection [A] *	12/6586 (0.18%)
Lung infection pseudomonal [A] *	1/6586 (0.02%)
Mastitis [A] *	1/6586 (0.02%)
Mastoiditis [A] *	1/6586 (0.02%)
Nasopharyngitis [A] *	1/6586 (0.02%)
Paronychia [A] *	1/6586 (0.02%)
Peritonitis bacterial [A] *	1/6586 (0.02%)
Pneumocystis jiroveci pneumonia [A] *	1/6586 (0.02%)
Pneumonia [A] *	217/6586 (3.29%)
Pneumonia primary atypical [A] *	2/6586 (0.03%)
Post procedural infection [A] *	1/6586 (0.02%)
Pyelonephritis [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Respiratory tract infection [A] *	14/6586 (0.21%)
Sepsis [A] *	17/6586 (0.26%)
Septic shock [A] *	6/6586 (0.09%)
Sinobronchitis [A] *	1/6586 (0.02%)
Skin infection [A] *	1/6586 (0.02%)
Tonsillitis [A] *	1/6586 (0.02%)
Tooth infection [A] *	1/6586 (0.02%)
Tracheobronchitis [A] *	1/6586 (0.02%)
Upper respiratory tract infection [A] *	4/6586 (0.06%)
Urinary tract infection [A] *	12/6586 (0.18%)
Urosepsis [A] *	2/6586 (0.03%)
Vulval abscess [A] *	1/6586 (0.02%)
Wound infection [A] *	1/6586 (0.02%)
Wound infection staphylococcal [A] *	1/6586 (0.02%)
Injury, poisoning and procedural complications	
Fall [A] *	6/6586 (0.09%)
Femoral neck fracture [A] *	7/6586 (0.11%)
Femur fracture [A] *	6/6586 (0.09%)
Fracture [A] *	1/6586 (0.02%)
Gastroenteritis radiation [A] *	1/6586 (0.02%)
Head injury [A] *	3/6586 (0.05%)
Hip fracture [A] *	2/6586 (0.03%)

	Erlotinib
	Affected/At Risk (%)
Humerus fracture [A] *	8/6586 (0.12%)
Joint dislocation [A] *	1/6586 (0.02%)
Limb injury [A] *	1/6586 (0.02%)
Multiple fractures [A] *	1/6586 (0.02%)
Overdose [A] *	1/6586 (0.02%)
Pelvic fracture [A] *	2/6586 (0.03%)
Procedural pain [A] *	1/6586 (0.02%)
Radiation pneumonitis [A] *	1/6586 (0.02%)
Radius fracture [A] *	1/6586 (0.02%)
Rib fracture [A] *	1/6586 (0.02%)
Road traffic accident [A] *	1/6586 (0.02%)
Skin laceration [A] *	1/6586 (0.02%)
Spinal compression fracture [A] *	2/6586 (0.03%)
Spinal fracture [A] *	1/6586 (0.02%)
Tendon rupture [A] *	1/6586 (0.02%)
Thermal burn [A] *	1/6586 (0.02%)
Thoracic vertebral fracture [A] *	1/6586 (0.02%)
Thrombosis in device [A] *	1/6586 (0.02%)
Transfusion reaction [A] *	1/6586 (0.02%)
Upper limb fracture [A] *	2/6586 (0.03%)
Wound complication [A] *	1/6586 (0.02%)
Wound dehiscence [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Wrist fracture [A] *	1/6586 (0.02%)
Investigations	
Aspiration pleural cavity [A] *	1/6586 (0.02%)
Blood creatinine increased [A] *	1/6586 (0.02%)
Bronchoalveolar lavage [A] *	1/6586 (0.02%)
Drug level increased [A] *	1/6586 (0.02%)
General physical condition abnormal [A] *	1/6586 (0.02%)
Haemoglobin decreased [A] *	2/6586 (0.03%)
Hepatic enzyme increased [A] *	2/6586 (0.03%)
International normalised ratio abnormal [A] *	1/6586 (0.02%)
International normalised ratio increased [A] *	2/6586 (0.03%)
Liver function test abnormal [A] *	1/6586 (0.02%)
Pulmonary function test decreased [A] *	1/6586 (0.02%)
Sigmoidoscopy [A] *	1/6586 (0.02%)
Weight decreased [A] *	7/6586 (0.11%)
Metabolism and nutrition disorders	
Anorexia [A] *	12/6586 (0.18%)
Cachexia [A] *	5/6586 (0.08%)
Dehydration [A] *	29/6586 (0.44%)
Diabetic ketoacidosis [A] *	1/6586 (0.02%)
Fluid overload [A] *	1/6586 (0.02%)
Hypercalcaemia [A] *	12/6586 (0.18%)

	Erlotinib
	Affected/At Risk (%)
Hyperglycaemia [A] *	2/6586 (0.03%)
Hyperglycaemic hyperosmolar nonketotic syndrome [A] *	1/6586 (0.02%)
Hyperkalaemia [A] *	2/6586 (0.03%)
Hypocalcaemia [A] *	1/6586 (0.02%)
Hypoglycaemia [A] *	9/6586 (0.14%)
Hypokalaemia [A] *	5/6586 (0.08%)
Hypomagnesaemia [A] *	1/6586 (0.02%)
Hyponatraemia [A] *	4/6586 (0.06%)
Malnutrition [A] *	1/6586 (0.02%)
Oral intake reduced [A] *	2/6586 (0.03%)
Tetany [A] *	1/6586 (0.02%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A] *	8/6586 (0.12%)
Arthritis [A] *	3/6586 (0.05%)
Back pain [A] *	36/6586 (0.55%)
Bone pain [A] *	26/6586 (0.39%)
Bursitis [A] *	3/6586 (0.05%)
Dactylitis [A] *	2/6586 (0.03%)
Flank pain [A] *	3/6586 (0.05%)
Joint destruction [A] *	1/6586 (0.02%)
Muscular weakness [A] *	11/6586 (0.17%)

	Erlotinib
	Affected/At Risk (%)
Musculoskeletal chest pain [A] *	2/6586 (0.03%)
Musculoskeletal pain [A] *	4/6586 (0.06%)
Neck pain [A] *	4/6586 (0.06%)
Osteolysis [A] *	1/6586 (0.02%)
Osteonecrosis [A] *	2/6586 (0.03%)
Osteoporotic fracture [A] *	1/6586 (0.02%)
Pain in extremity [A] *	7/6586 (0.11%)
Pathological fracture [A] *	7/6586 (0.11%)
Spondylolisthesis [A] *	1/6586 (0.02%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Basal cell carcinoma [A] *	1/6586 (0.02%)
Breast cancer [A] *	1/6586 (0.02%)
Bronchial carcinoma [A] *	1/6586 (0.02%)
Bronchial neoplasm [A] *	1/6586 (0.02%)
Bronchioloalveolar carcinoma [A] *	1/6586 (0.02%)
Cancer pain [A] *	1/6586 (0.02%)
Gastrointestinal neoplasm [A] *	1/6586 (0.02%)
Intracranial tumour haemorrhage [A] *	2/6586 (0.03%)
Lung adenocarcinoma [A] *	1/6586 (0.02%)
Lung cancer metastatic [A] *	4/6586 (0.06%)
Lung neoplasm malignant [A] *	40/6586 (0.61%)
Lymphangiosis carcinomatosa [A] *	3/6586 (0.05%)

	Erlotinib
	Affected/At Risk (%)
Malignant ascites [A] *	1/6586 (0.02%)
Malignant melanoma [A] *	1/6586 (0.02%)
Malignant neoplasm progression [A] *	4/6586 (0.06%)
Malignant pleural effusion [A] *	6/6586 (0.09%)
Metastases to abdominal wall [A] *	1/6586 (0.02%)
Metastases to bone [A] *	11/6586 (0.17%)
Metastases to central nervous system [A] *	54/6586 (0.82%)
Metastases to heart [A] *	2/6586 (0.03%)
Metastases to liver [A] *	3/6586 (0.05%)
Metastases to meninges [A] *	3/6586 (0.05%)
Metastases to peritoneum [A] *	1/6586 (0.02%)
Metastases to skin [A] *	2/6586 (0.03%)
Metastases to spine [A] *	6/6586 (0.09%)
Metastasis [A] *	1/6586 (0.02%)
Metastatic neoplasm [A] *	2/6586 (0.03%)
Metastatic pain [A] *	6/6586 (0.09%)
Neoplasm malignant [A] *	1/6586 (0.02%)
Neoplasm progression [A] *	25/6586 (0.38%)
Neoplasm recurrence [A] *	1/6586 (0.02%)
Non-small cell lung cancer [A] *	810/6586 (12.3%)
Non-small cell lung cancer Stage IIIB [A] *	1/6586 (0.02%)
Non-small cell lung cancer metastatic [A] *	9/6586 (0.14%)

	Erlotinib
	Affected/At Risk (%)
Paraneoplastic syndrome [A] *	1/6586 (0.02%)
Pericardial effusion malignant [A] *	1/6586 (0.02%)
Pericarditis malignant [A] *	1/6586 (0.02%)
Prostate cancer [A] *	2/6586 (0.03%)
Tumour associated fever [A] *	3/6586 (0.05%)
Tumour haemorrhage [A] *	1/6586 (0.02%)
Tumour necrosis [A] *	1/6586 (0.02%)
Tumour pain [A] *	7/6586 (0.11%)
Nervous system disorders	
Altered state of consciousness [A] *	3/6586 (0.05%)
Aphasia [A] *	5/6586 (0.08%)
Ataxia [A] *	1/6586 (0.02%)
Brain oedema [A] *	5/6586 (0.08%)
Cerebral haemorrhage [A] *	4/6586 (0.06%)
Cerebral infarction [A] *	11/6586 (0.17%)
Cerebral ischaemia [A] *	4/6586 (0.06%)
Cerebrovascular accident [A] *	24/6586 (0.36%)
Coma [A] *	1/6586 (0.02%)
Convulsion [A] *	13/6586 (0.2%)
Depressed level of consciousness [A] *	2/6586 (0.03%)
Diplegia [A] *	1/6586 (0.02%)
Dizziness [A] *	8/6586 (0.12%)

	Erlotinib
	Affected/At Risk (%)
Encephalopathy [A] *	1/6586 (0.02%)
Epilepsy [A] *	4/6586 (0.06%)
Facial paresis [A] *	1/6586 (0.02%)
Grand mal convulsion [A] *	1/6586 (0.02%)
Headache [A] *	6/6586 (0.09%)
Hemiparesis [A] *	6/6586 (0.09%)
Hemiplegia [A] *	4/6586 (0.06%)
Hepatic encephalopathy [A] *	1/6586 (0.02%)
Hydrocephalus [A] *	1/6586 (0.02%)
Hypoaesthesia [A] *	1/6586 (0.02%)
Hypoglycaemic coma [A] *	1/6586 (0.02%)
Intracranial pressure increased [A] *	2/6586 (0.03%)
Ischaemic stroke [A] *	2/6586 (0.03%)
Lethargy [A] *	1/6586 (0.02%)
Leukoencephalopathy [A] *	1/6586 (0.02%)
Loss of consciousness [A] *	2/6586 (0.03%)
Memory impairment [A] *	1/6586 (0.02%)
Meningeal disorder [A] *	1/6586 (0.02%)
Mental impairment [A] *	1/6586 (0.02%)
Metabolic encephalopathy [A] *	1/6586 (0.02%)
Monoparesis [A] *	3/6586 (0.05%)
Monoplegia [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Myelopathy [A] *	1/6586 (0.02%)
Myoclonus [A] *	1/6586 (0.02%)
Nerve root compression [A] *	1/6586 (0.02%)
Nervous system disorder [A] *	1/6586 (0.02%)
Neurological symptom [A] *	2/6586 (0.03%)
Neuropathy peripheral [A] *	2/6586 (0.03%)
Paraesthesia [A] *	2/6586 (0.03%)
Paraparesis [A] *	4/6586 (0.06%)
Paraplegia [A] *	3/6586 (0.05%)
Partial seizures [A] *	2/6586 (0.03%)
Peripheral motor neuropathy [A] *	2/6586 (0.03%)
Peripheral paralysis [A] *	1/6586 (0.02%)
Polyneuropathy [A] *	1/6586 (0.02%)
Presyncope [A] *	1/6586 (0.02%)
Psychomotor hyperactivity [A] *	1/6586 (0.02%)
Psychomotor skills impaired [A] *	1/6586 (0.02%)
Quadriplegia [A] *	1/6586 (0.02%)
Radicular pain [A] *	1/6586 (0.02%)
Sciatica [A] *	1/6586 (0.02%)
Somnolence [A] *	2/6586 (0.03%)
Spinal cord compression [A] *	12/6586 (0.18%)
Spinal cord disorder [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Subdural hygroma [A] *	1/6586 (0.02%)
Syncope [A] *	19/6586 (0.29%)
Syncope vasovagal [A] *	2/6586 (0.03%)
Transient ischaemic attack [A] *	7/6586 (0.11%)
Psychiatric disorders	
Agitation [A] *	1/6586 (0.02%)
Alcohol abuse [A] *	1/6586 (0.02%)
Alcohol withdrawal syndrome [A] *	1/6586 (0.02%)
Anxiety [A] *	2/6586 (0.03%)
Completed suicide [A] *	1/6586 (0.02%)
Confusional state [A] *	26/6586 (0.39%)
Delirium [A] *	3/6586 (0.05%)
Depression [A] *	6/6586 (0.09%)
Disorientation [A] *	1/6586 (0.02%)
Eating disorder [A] *	1/6586 (0.02%)
Suicide attempt [A] *	1/6586 (0.02%)
Vomiting psychogenic [A] *	1/6586 (0.02%)
Renal and urinary disorders	
Calculus urinary [A] *	1/6586 (0.02%)
Dysuria [A] *	1/6586 (0.02%)
Glomerulosclerosis [A] *	1/6586 (0.02%)
Haematuria [A] *	7/6586 (0.11%)

	Erlotinib
	Affected/At Risk (%)
Nephrolithiasis [A] *	1/6586 (0.02%)
Renal colic [A] *	1/6586 (0.02%)
Renal failure [A] *	6/6586 (0.09%)
Renal failure acute [A] *	2/6586 (0.03%)
Renal failure chronic [A] *	1/6586 (0.02%)
Urinary incontinence [A] *	1/6586 (0.02%)
Urinary retention [A] *	5/6586 (0.08%)
Reproductive system and breast disorders	
Cervical polyp [A] *	1/6586 (0.02%)
Pelvic pain [A] *	1/6586 (0.02%)
Uterine haemorrhage [A] *	1/6586 (0.02%)
Respiratory, thoracic and mediastinal disorders	
Acute interstitial pneumonitis [A] *	1/6586 (0.02%)
Acute pulmonary oedema [A] *	1/6586 (0.02%)
Acute respiratory distress syndrome [A] *	2/6586 (0.03%)
Acute respiratory failure [A] *	10/6586 (0.15%)
Alveolitis [A] *	1/6586 (0.02%)
Asphyxia [A] *	1/6586 (0.02%)
Atelectasis [A] *	3/6586 (0.05%)
Bronchial haemorrhage [A] *	1/6586 (0.02%)
Bronchial obstruction [A] *	2/6586 (0.03%)
Bronchopleural fistula [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Bronchospasm [A] *	1/6586 (0.02%)
Bronchostenosis [A] *	1/6586 (0.02%)
Chronic obstructive pulmonary disease [A] *	15/6586 (0.23%)
Cough [A] *	7/6586 (0.11%)
Dyspnoea [A] *	340/6586 (5.16%)
Dyspnoea at rest [A] *	1/6586 (0.02%)
Epistaxis [A] *	1/6586 (0.02%)
Haemoptysis [A] *	83/6586 (1.26%)
Haemothorax [A] *	3/6586 (0.05%)
Hydropneumothorax [A] *	2/6586 (0.03%)
Hypoxia [A] *	3/6586 (0.05%)
Interstitial lung disease [A] *	5/6586 (0.08%)
Lung disorder [A] *	3/6586 (0.05%)
Lung infiltration [A] *	3/6586 (0.05%)
Obstructive airways disorder [A] *	1/6586 (0.02%)
Orthopnoea [A] *	1/6586 (0.02%)
Pleural disorder [A] *	2/6586 (0.03%)
Pleural effusion [A] *	107/6586 (1.62%)
Pleurisy [A] *	3/6586 (0.05%)
Pleuritic pain [A] *	1/6586 (0.02%)
Pleurocutaneous fistula [A] *	1/6586 (0.02%)
Pneumonia aspiration [A] *	2/6586 (0.03%)

	Erlotinib
	Affected/At Risk (%)
Pneumonitis [A] *	16/6586 (0.24%)
Pneumothorax [A] *	17/6586 (0.26%)
Productive cough [A] *	1/6586 (0.02%)
Pulmonary artery thrombosis [A] *	1/6586 (0.02%)
Pulmonary embolism [A] *	68/6586 (1.03%)
Pulmonary fibrosis [A] *	1/6586 (0.02%)
Pulmonary haemorrhage [A] *	9/6586 (0.14%)
Pulmonary infarction [A] *	1/6586 (0.02%)
Pulmonary mass [A] *	1/6586 (0.02%)
Pulmonary oedema [A] *	8/6586 (0.12%)
Respiratory arrest [A] *	1/6586 (0.02%)
Respiratory disorder [A] *	1/6586 (0.02%)
Respiratory distress [A] *	5/6586 (0.08%)
Respiratory failure [A] *	115/6586 (1.75%)
Respiratory tract congestion [A] *	1/6586 (0.02%)
Stridor [A] *	1/6586 (0.02%)
Tracheal disorder [A] *	1/6586 (0.02%)
Skin and subcutaneous tissue disorders	
Acne [A] *	1/6586 (0.02%)
Decubitus ulcer [A] *	1/6586 (0.02%)
Erythema [A] *	1/6586 (0.02%)
Livedo reticularis [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Palmar-plantar erythrodysaesthesia syndrome [A] *	2/6586 (0.03%)
Pemphigoid [A] *	1/6586 (0.02%)
Rash [A] *	32/6586 (0.49%)
Skin necrosis [A] *	1/6586 (0.02%)
Skin ulcer [A] *	2/6586 (0.03%)
Stasis dermatitis [A] *	1/6586 (0.02%)
Urticaria [A] *	1/6586 (0.02%)
Urticaria chronic [A] *	1/6586 (0.02%)
Surgical and medical procedures	
Angioplasty [A] *	1/6586 (0.02%)
Hip arthroplasty [A] *	1/6586 (0.02%)
Jaw operation [A] *	1/6586 (0.02%)
Pain management [A] *	1/6586 (0.02%)
Pleurodesis [A] *	1/6586 (0.02%)
Rehabilitation therapy [A] *	1/6586 (0.02%)
Renal stone removal [A] *	1/6586 (0.02%)
Spinal decompression [A] *	1/6586 (0.02%)
Thoracic cavity drainage [A] *	1/6586 (0.02%)
Vascular disorders	
Aneurysm [A] *	2/6586 (0.03%)
Aortic aneurysm rupture [A] *	1/6586 (0.02%)
Arterial insufficiency [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Arterial occlusive disease [A] *	1/6586 (0.02%)
Arterial thrombosis [A] *	1/6586 (0.02%)
Arterial thrombosis limb [A] *	4/6586 (0.06%)
Axillary vein thrombosis [A] *	2/6586 (0.03%)
Cardiovascular insufficiency [A] *	3/6586 (0.05%)
Circulatory collapse [A] *	5/6586 (0.08%)
Deep vein thrombosis [A] *	31/6586 (0.47%)
Embolism [A] *	4/6586 (0.06%)
Haemorrhage [A] *	3/6586 (0.05%)
Hypertension [A] *	3/6586 (0.05%)
Hypotension [A] *	1/6586 (0.02%)
Hypovolaemic shock [A] *	1/6586 (0.02%)
Intermittent claudication [A] *	2/6586 (0.03%)
Ischaemia [A] *	1/6586 (0.02%)
Lymphoedema [A] *	1/6586 (0.02%)
Macroangiopathy [A] *	1/6586 (0.02%)
Orthostatic hypotension [A] *	2/6586 (0.03%)
Pelvic venous thrombosis [A] *	1/6586 (0.02%)
Peripheral arterial occlusive disease [A] *	1/6586 (0.02%)
Peripheral embolism [A] *	1/6586 (0.02%)
Peripheral ischaemia [A] *	2/6586 (0.03%)
Shock [A] *	1/6586 (0.02%)

	Erlotinib
	Affected/At Risk (%)
Shock haemorrhagic [A] *	1/6586 (0.02%)
Subclavian artery stenosis [A] *	1/6586 (0.02%)
Subclavian vein thrombosis [A] *	2/6586 (0.03%)
Superior vena caval occlusion [A] *	11/6586 (0.17%)
Thrombophlebitis [A] *	2/6586 (0.03%)
Thrombophlebitis superficial [A] *	1/6586 (0.02%)
Thrombosis [A] *	7/6586 (0.11%)
Vascular rupture [A] *	1/6586 (0.02%)
Vena cava thrombosis [A] *	1/6586 (0.02%)
Venous occlusion [A] *	1/6586 (0.02%)
Venous thrombosis limb [A] *	2/6586 (0.03%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (11.0)

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Erlotinib
	Affected/At Risk (%)
Total	0/6586 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

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